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Magazine, G-1

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JOINT INVESTIGATION BY PG AND PROPUBLICA — PART 1 IN A SERIES

WITH EVERY BREATH

MILLIONS OF MACHINES, ONE DANGEROUS DEFECT

Benjamin B. Braun/Post-Gazette

Mark Edwards, a 58-year-old retired music teacher and father of three, sleeps with a recalled sleep apnea machine made by Philips Respironics the night before his surgery in Florida to remove a second tumor from his throat.

Philips kept complaints about dangerous breathing devices secret while its profits soared

By Michael D. Sallah, Michael Korsh and Evan Robinson-Johnson
Pittsburgh Post-Gazette

Debbie Cenziper
ProPublica

Monica Sager
Northwestern University

The first complaints landed at the offices of Philips Respironics in 2010, soon after the company made a fateful decision to redesign its bestselling breathing machines used in homes and hospitals around the world.

To silence the irritating rattle that kept users awake at night, Philips packed the devices with an industrial foam — the same kind used in sofas and mattresses. It quickly became clear that something had gone terribly wrong.

The reports coming into Philips described "black particles" or "dirt and dust" inside machines that pump air to those who struggle to breathe. One noted an "oily-like" substance. Others simply warned of "contamination."

The complaints targeted some of the company's most-celebrated devices built in two factories near Pittsburgh, including ventilators for the sick and dying and the popular DreamStation for patients who suffer from sleep apnea, a chronic disorder that causes breathing to stop and start throughout the night.

Yet Philips withheld the vast majority of the warnings from the Food and Drug Administration, even as their numbers grew from dozens to hundreds to thousands and became more alarming each year.

"Black shavings in the chamber," said one 2011 report that was kept from the government. "Contaminated with unknown sticky substance," noted another three years later. By 2015, the year Philips launched the DreamStation, the company had amassed at least 25 complaints that pointed to a specific cause — the foam was falling apart.

In June 2021, more than a decade after the first reports,

SEE **CPAP**, PAGE A-11

Merlin Daleman

Complaints poured into Philips that the foam inserted in the breathing devices since 2008 to reduce noise was breaking down, and could potentially be releasing toxic fumes into the lungs.

By the numbers

11
Years between first complaints to Philips and 2021 recall

370
Death cases reported to the Food and Drug Administration

3,700
Complaints withheld from FDA by Philips (2010-2021)

Sources: Reports to Food and Drug Administration, and Device Events

6 PAGES INSIDE

- Local woman using husband's death to crusade for him, others. **Page A-12**
- Timeline of one of largest recalls of its kind. **A-13-15**
- What is sleep apnea? **H-1**

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- **LEGAL TRAIL:** Tracing cases filed in U.S. cities and globally.
- **IN THEIR WORDS:** Families and the company's founder share their stories in video.

GOVERNMENT SHUTDOWN

Senate passes stopgap measure

McCarthy's efforts rewarded in House

By Jonathan D. Salant
Pittsburgh Post-Gazette

WASHINGTON — Congress averted a government shutdown with just hours to go Saturday, avoiding layoffs for thousands of federal employees in Pennsylvania and preserving federal nutrition aid for close to 180,000 low-income residents in the Keystone State.

The breakthrough came when House Speaker Kevin McCarthy abandoned his efforts to pass a bill with just Republican votes in a narrowly divided chamber and instead offered a measure funding the government at current spending levels for 45 days, giving lawmakers time to pass the appropriations measures funding federal agencies through Sept. 30, 2024.

Mr. McCarthy's temporary spending bill, known as a continuing resolution, sailed through his chamber with a majority of both Republicans and Democrats.

The U.S. Senate on Saturday night overwhelmingly voted in favor of the bill, 88-9, ahead of the midnight deadline to avoid a government shutdown.

President Joe Biden, who said in

SEE **SHUTDOWN**, PAGE A-9

Shapiro broadens message

Tells N.H. Democrats: 'We can do big things'

By Ford Turner
Pittsburgh Post-Gazette

Shapiro

BEDFORD, N.H. — Far outside the state he leads but well inside the national political environment he courts, Pennsylvania Gov. Josh Shapiro told New Hampshire Democrats on Saturday that his administration has shown America "we can do big things," and that Democrats understand winning elections "is just the beginning."

"We showed that we can do big things again here in America and I think that's who we are as Democrats," Mr. Shapiro said. "That's the attitude we need to bring every single day across this nation. We get things done for the good people of this country."

Mr. Shapiro appeared at the New Hampshire Democratic

SEE **SHAPIRO**, PAGE A-9

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Weather
Daytime high, 80; tonight's low, 57.
Page B-16

Almanac A-2
Books D-5
Bridge G-8
Business E-1
Crosswords G-8
Editorials D-2
Goodness F-1
Health H-1
Horoscope G-6
Insight D-1
Jobs E-5
Lottery A-18
Mortgages G-6
Obituaries C-5
Real Estate G-4
Sports B-1
State & Region C-1
Sunday Magazine ... G-1
Television G-3
Traffic Watch C-2

6 08136 26303 2

JOINT INVESTIGATION BY PG AND PROPUBLICA | WITH EVERY BREATH | WWW.POST-GAZETTE.COM/ROYALPHILIPS

Liz Moughon/ProPublica

The DreamStation, a continuous positive airway pressure (CPAP) machine, was among the signature devices made by Philips Respironics and part of one of the largest recalls of its kind.

U.S. District Court of Western Pa. exhibit

The foam breaks down into particles, as shown in this photo that was attached to an email sent by a concerned Philips engineer to the company's foam supplier in 2018.

MILLIONS OF DEVICES, ONE DANGEROUS DEFECT

Arturo Fernandez/Post-Gazette

Respironics founder Gerald McGinnis, a Pittsburgh inventor and mechanical engineer, helped develop one of the first mass produced CPAPs in the world. "I felt like I lost my third daughter," he said after the company was sold to Royal Philips in 2008.

CPAP, FROM A-1

Philips announced a recall of millions of machines that had been delivered to nearly every corner of the United States and dozens of other countries. The company acknowledged that the foam it had chosen could crumble in heat and humidity and send potentially "toxic and carcinogenic" material into the noses, mouths, throats and lungs of users.

In a series of statements, the industry giant said it acted as soon as it learned of the "potential significance" of the problem.

But an investigation by the Pittsburgh Post-Gazette and ProPublica of the 11 years between the first complaints and the recall reveals a different story — one of a company that sought to protect its marquee products as stock prices soared to the highest levels in decades.

Again and again, previously undisclosed records and interviews with company insiders show, Philips suppressed mounting evidence that its profitable breathing machines threatened the health of the people relying on them, in some cases to stay alive.

Federal law requires device makers to turn over to the government within 30 days all reports of patient injuries, deaths and malfunctions that have the potential to cause harm, and to take action to investigate them.

A Post-Gazette and ProPublica analysis of tens of thousands of reports shows that Philips withheld more than 3,700 complaints over 11 years from the FDA, which oversees medical devices.

And the company did not launch a formal investigation of the problem until 2019 — nine years after the first wave of complaints and three years after the first known tests for the company found that the foam was degrading.

Instead, as the complaints continued to pile up in company files, Philips waged aggressive global marketing campaigns to sell more machines, including new models fitted with the hazardous foam.

The sales pitch worked: The devices went to infants, the elderly and at least 700,000 veterans. The company also promoted machines meant for some of the sickest people in the country, rolling out a new ventilator filled with the foam in the early months of the COVID-19 pandemic.

Philips didn't stop even after an investigation in Japan found the foam was breaking down in the company's ventilators and had to be replaced — and after tests in the United States revealed the material released dangerous chemicals. Among them: formaldehyde, a compound used in fertilizer, dyes and glues that has been tied to respiratory problems and, at high exposure levels, certain cancers.

> **"It was a catastrophic series of errors. There were people who knew and knew for a long time."**
>
> **Former Philips compliance supervisor**

In 2018, the company called more than a dozen engineers and safety supervisors to a series of urgent meetings in Pittsburgh to investigate the problem in what eventually became known to insiders as Project Uno.

Still, the public was not warned.

All the while, people using Philips machines were suffering from illnesses that no one could explain: vomiting, dizziness and headaches, along with newly diagnosed cancers of the lungs, throat, sinuses and esophagus. One man in Philadelphia coughed so hard that he broke his ribs, and a Florida woman with a hacking cough was hospitalized for days and placed on oxygen.

"Unconscionable," said Dr. Radhika Breaden, who scrambled at her Oregon sleep clinic to help thousands of patients who were using the devices. "We were all completely blindsided. You can't have people inhaling black dust … without warning us."

To examine what happened at Philips, reporters interviewed more than 200 former company supervisors, doctors, toxicologists, patients and the relatives of those who died, and obtained company records that show officials knew about the dangers but continued to sell machines the FDA has since said are capable of causing severe illness or death.

Reporters also reviewed thousands of complaints submitted to the company and government describing device malfunction and injuries, including more than 370 reports of deaths. As part of the investigation, the news organizations collaborated with Mediahuis NRC, the publisher of one of the largest newspapers in the Netherlands, where Philips' parent company is located.

In a statement to the news organizations, Philips said its top priority is patient safety and that it regretted "the distress and concern" caused by the recall. "We deeply apologize for that and continue to work hard to resolve this," the company said.

Philips said complaints about the foam were limited in the years before the recall and that the reports were evaluated on a case-by-case basis. The company added that it became aware of the potential significance of the problem in early 2021 and launched the recall shortly after that.

Former company engineers and safety supervisors, who spoke on the condition of anonymity because they still work in the industry, said top officials at Philips repeatedly dismissed a dangerous breakdown that ultimately set off a worldwide health crisis involving as many as 15 million devices.

"It was a catastrophic series of errors," said a former compliance supervisor. "There were people who knew and knew for a long time."

In the months since the recall, the company has walked back its acknowledgement of the health risks posed by the degrading foam, saying tests on the DreamStation and similar devices show the chemicals released by the material fall within safety thresholds.

"The whole product complies with safety norms," Roy Jakobs, chief executive officer of parent company Royal Philips, said last year.

The Post-Gazette and ProPublica obtained copies of four tests carried out in 2021 that were solicited by Philips. Three experts who reviewed the results for the news organizations dispute the company's claim and point to another finding that they say is even more alarming.

The foam tested positive multiple times for genotoxicity — the ability of a chemical to cause cells to mutate, a process that can lead to cancer.

"You're basically changing cells," said one engineer who was involved in the testing and summarized the results. "I don't even know if we really scratched the surface of how bad this really is."

In New York, 58-year-old retired music teacher and father of three Mark Edwards said he'll spend the rest of his life fearing that a sleep apnea machine caused years of respiratory infections and two benign tumors in his throat.

Mr. Edwards brought home a DreamStation in 2017 and set it up next to his bed, where he sleeps with his rescued German shepherd, Tyson. He continued using it even after he said he began to spot black particles in his mask.

"I would wash it and use hot water, and then two days later, I would see it again," he said.

After his machine was recalled, Mr. Edwards sued the company, one of tens of thousands of people joining litigation against the company in federal court in Pittsburgh.

Mr. Edwards stopped using the device earlier this year and said his respiratory infections went away, but in April, he traveled to Florida to undergo a second surgery on his throat. As he waited in the hospital with his sister, he clutched a gold crucifix around his neck.

"If something happens to me in surgery, I'm ready to go," he said, and then he was wheeled off to the operating room.

A COMPETITIVE EDGE

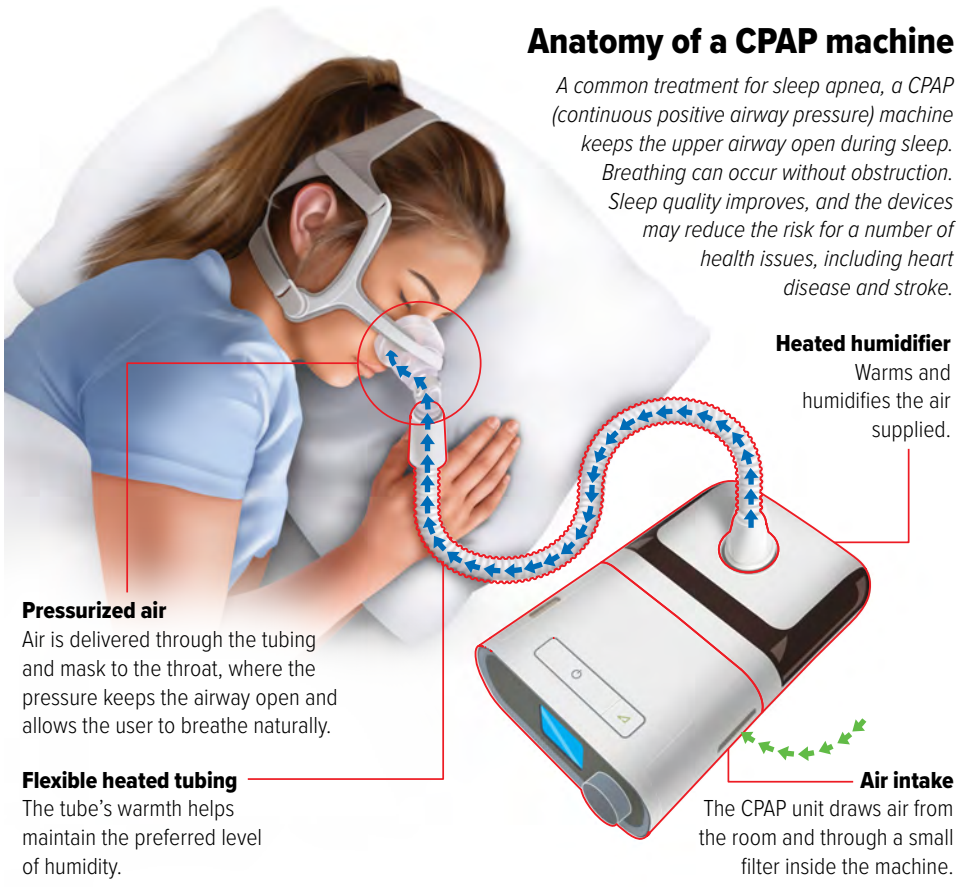
Years before the crisis, inventor Gerald McGinnis sat in his suburban Pittsburgh kitchen next to an avocado-green stove and Betty Crocker cookbooks, fretting about patients forced to breathe through tubes inserted into their windpipes.

The mechanical engineer

SEE **CPAP**, PAGE A-13

Anatomy of a CPAP machine

A common treatment for sleep apnea, a CPAP (continuous positive airway pressure) machine keeps the upper airway open during sleep. Breathing can occur without obstruction. Sleep quality improves, and the devices may reduce the risk for a number of health issues, including heart disease and stroke.

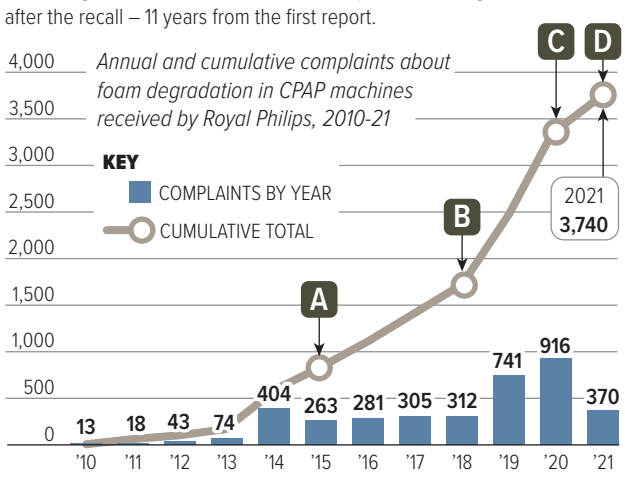


Source: Royal Philips

James Hilston, Ed Yozwick/Post-Gazette

Philips received 3,700 complaints about contaminants in breathing machines

The medical device maker began using polyester-based polyurethane foam in its ventilators and CPAPs to reduce noise more than a decade ago. The company was barraged with reports of "debris," "black particles" and "foam degradation," but held back the complaints from regulators until after the recall – 11 years from the first report.



A **2015:** Philips receives complaints about ventilators in Japan. Tests show that the foam fitted inside the machines could break down in heat and humidity, releasing particles into the masks worn by patients.

B **2018:** In an email, a mechanical engineer at Philips acknowledges the foam is "disintegrating," and wrote "This is not a good situation for our users."

C **2020:** Some of the company's top supervisors take part in health hazard evaluations, which find that the crumbling foam and released chemicals could cause "serious injury, life-threatening or permanent impairment."

D **2021:** After recall, Philips turns over past complaints dating back to at least since 2010

Source: Device Events, a Pennsylvania company that extracts federal data from the Food and Drug Administration's adverse events tracking system known as Manufacturer and User Facility Device Experience (MAUDE)

James Hilston/Post-Gazette

Benjamin B. Braun/Post-Gazette photos

Cindy and Bruce Pogyor celebrate an anniversary in a family photo. The Pogyors were married for nearly 50 years, before Bruce succumbed to lung cancer in late 2020.

MEMORIES AND A MISSION

Philips recall of hazardous breathing machines serves as a painful reminder for Elizabeth widow, but she vows to 'be a voice for him' and others

By Jordan Anderson
Pittsburgh Post-Gazette

A year and a half after Cindy Pogyor said goodbye to her husband as he lay dying from the lung cancer that had spread to his brain, the box arrived at her home outside Pittsburgh.

It was a Philips Respironics breathing machine — a replacement for the same ones he had used every night for seven years.

She reached into the container, pulled out the device, and tossed it into the garage.

Her 72-year-old husband, Bruce, never knew that his machine along with millions of others had been pulled from the shelves because of a dangerous flaw, one that the company and the federal government said could cause severe injuries and even death.

In June 2021, eight months after Bruce died, Philips Respironics had announced that foam placed inside the devices to insulate sound was breaking down under heat and moisture and potentially releasing highly toxic fumes into the lungs of sleeping patients.

Now, living alone in a ranch home at the end of a quiet street in Elizabeth Township, she said she wrestles with wrenching questions over whether the machine — built in a Philips factory just miles from their home — caused the disease that led to years of painful surgeries and treatments.

For months, Ms. Pogyor watched her husband of nearly 50 years slowly waste away, even as he used the DreamStation continuous positive airway pressure machine — or CPAP — that he thought was helping to sustain his life.

"We relied on the usage of [those machines], not knowing that it could be harmful," said the 75-year-old widow, who is consulting with a Pittsburgh law firm about joining in personal injury litigation against Philips that alleges the company knew of the hazards years before it yanked the devices from the market. "How could they?"

At the start of the recall, Philips said the potential health risks of the devices could lead to serious injury "which can be life threatening" and then later backed off that disclosure, saying that further testing did not show any long-term danger.

But the Food and Drug Administration has called into question several of the company's tests and says it has received at least 385 reports of deaths of people who used the machines in what experts say could be one of the deadliest recalls of medical devices in U.S. history.

For the past year, Ms. Pogyor says she has been on a mission to gather details about the dangers of the machine — and how she can be a voice for her husband. who never knew anything about them.

The couple met more than 60 years ago when both were in the fifth grade in West Mifflin — her curly hair catching his attention, she said.

They married while he finished his studies at what is now Robert Morris University, and later moved to Elizabeth in 1975 to build their lives around their extended family and friends.

Ms. Pogyor worked for Trans World Airlines, while her husband launched a career in food sales. Even in the years they lived paycheck to paycheck, they would scrounge up money to travel, often visiting family in Southern California and spending countless hours at the beach.

"We did everything together," she said.

Cindy Pogyor says she is on a mission to ensure her husband's death provides insights for others.

Cindy Pogyor displays keepsakes of her husband, Bruce.

In their retirement, the couple didn't slow down. They held season tickets for the Pittsburgh Pirates, visited casinos to play keno, and attended musicals like "The Buddy Holly Story" and "Jersey Boys" at the Benedum Center for the Performing Arts.

Though they never had their own children, they embraced their nieces and nephews like they were their own.

After his diagnosis of sleep apnea in 2012, he used his DreamStation machine faithfully and cleaned it regularly, at times with an ozone cleaner — a substance that Philips blames for much of the problem with the foam.

But even the FDA, which has been highly critical of Philips over its handling of the recall, says the breakdown is due to the foam, and not the ozone cleaner.

In 2018, during a scan of his heart, doctors found spots on his lungs. At first, they thought he had pneumonia and treated him with antibiotics. When the spots didn't go away, a lung biopsy confirmed it was cancer.

Slowly, week by week, the disease broke him down. During a period after radiation, he passed out eight times in five months, his wife recalled.

He would sometimes collapse in public without warning and could no longer take part in activities that he loved, like golf, his favorite sport since he was 12.

"He wasn't able to do anything at all," said Ms. Pogyor.

His family struggled to cope. Known as "Uncle Smooth" — a name that stuck when he was waxing a car with his nephew — he could no longer attend family dinners or other events. Before, he rarely missed his nephew's football games.

"My kids just adored him," said Joyce Tarabrella, his sister who lives just a block away.

In time, the disease metastasized and spread to other parts of his body. In his last month, Mr. Pogyor underwent brain surgery. Initially, recovery was going well, and he was set to stay at UPMC East in Monroeville for about three weeks.

But he died Oct. 26, 2020, just three days before he was scheduled to go home.

In June 2021, less than a year after his death, the company issued the massive recall for its breathing devices. Ms. Pogyor said she remembers receiving a notification in the mail. She dismissed it.

"It was like my husband's past," she said.

Then she got another one, and then a third.

The final notification pushed her to go online and learn more about the foam and potential health risks. "Possible toxic and carcinogenic effects," the company said in its recall announcement. She felt horrified, angry, by what she read.

Not only was her husband's first CPAP machine filled with the problem foam, but a second one he began using in 2019 was also fitted with the same material.

"They knew of this situation for years and failed to act, notify the public," Ms. Pogyor said.

In May 2022, she received the new DreamStation machine, a replacement meant for her husband.

"My husband's deceased, why are you even sending this?" she recalled saying at the time.

All these months later, she said she's left to think about a life that feels unfinished, cut short.

She said she still talks to her husband every day. From time to time, she looks through a folder full of keepsakes, including the birthday cards he crafted out of envelopes when he became sick and couldn't drive anymore. He always wanted to give her something.

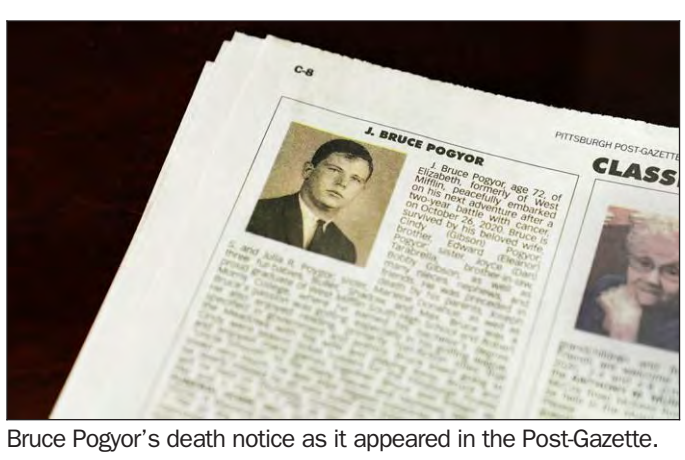
On what was to be their 50th wedding anniversary, she flipped through their old photos, just like they used to do together each year. Nearby was the camouflage urn holding his ashes at her bedside and the framed wedding photos behind it.

"You can be in a room full of people and still feel alone," she said. "You don't realize how much noise the house makes when you're the only one in it."

Ultimately, she says she will devote whatever time it takes to make sure her husband's case and those of others are heard.

"I thought I had to be a voice for him," she said. "He was one that didn't back down, you know; he had always pushed me to speak my mind. And I thought I had to do that for him."

Jordan Anderson: janderson@post-gazette.com



Bruce Pogyor's death notice as it appeared in the Post-Gazette.

TELL US YOUR STORY

If you've been affected by the recall of 15 million of Royal Philips' breathing devices, we'd like to hear about your experience. Scan this code to share your insights.

CPAP, FROM A-11

knew he could create something better.

Throughout the 1980s, Mr. McGinnis invented a series of breathing masks and ultimately developed the nation's first mass-produced continuous positive airway pressure, or CPAP, machine, sold under the banner of his growing company, Respironics.

During a scientific renaissance that transformed Pittsburgh from a steel town into a hub for medical innovation, the company became a dominant player in a thriving industry that would change the lives of those struggling with sleep apnea.

For the millions of people impacted by the condition, CPAP machines were game-changers, allowing them to breathe normally at night — often for the first time in years.

"It was the gift from heaven," said Mr. McGinnis, now 89, whose company grew to 4,900 employees and more than $1 billion in revenue by 2007.

Everything changed when Royal Philips, the conglomerate known for light bulbs and televisions, showed up at his door, he said in an interview with the Post-Gazette and ProPublica.

The company from Amsterdam had just purchased several medical equipment companies in the United States and aimed to take over Respironics. At first, Respironics rejected the Dutch company's bid, but finally agreed to sell in 2007 under the threat of a takeover, Mr. McGinnis said.

"They said, 'We want to buy the company, regardless, whether you want to do it the hard way or the easy way,'" said Mr. McGinnis, then board chairman. "In less than six months, they cleaned us out. I felt like I lost my third daughter."

Soon after taking control of the Pittsburgh company, the new subsidiary called Philips Respironics made a critical decision.

Locked in a race to make its breathing machines quieter, the company began to insert the foam to muffle sound. The change was a triumph in the world of sleep apnea, a way to quiet the humming, vibrating machines that disturbed patients and their partners as they slept.

Unlike its top competitor, which chose a different foam to quiet the machines, Philips selected one made of polyester-based polyurethane, the same kind of material used in furniture, shoes and other products.

Though it is unclear why the company chose the material, Philips noted in a 2009 patent that older solutions to reduce sound were "ineffective, inefficient and/or expensive."

It was a risky move. Tests published in scholarly journals showed the foam broke apart in heat and moisture. The company used it anyway, even in machines with heated humidifiers.

"Anybody who has half a brain cell in chemistry knows that this was a stupid idea," said the engineer who was involved in the recent testing.

Soon, alarming reports began to surface.

In June 2010, Philips found that a machine sent back to the company by a customer was contaminated with "foam particles," FDA records show. Rather than alerting the government as federal law required, records reveal that the company kept the report about the problem in-house for the next decade.

A similar report came in the following year, describing another CPAP with "black contamination." That, too, was not turned over to federal regulators.

Another report was also held back, this one from a patient who found particles in the tube that carries air to the nose and mouth. A complaint two years later described a 3-year-old girl who was using a ventilator with a filter that had turned black.

By the end of 2014 — about five years after Philips started using the foam — more than 500 reports from health care workers, patients and others had flooded the company in a pattern that would not be revealed to the government or the public for years, the records show.

Philips said the company had previously determined that the complaints about the foam did not need to be reported but later changed course and turned them over "out of an abundance of caution" after the FDA got involved.

In an email, the FDA confirmed that the company "was in possession of numerous complaints" that should have been submitted to the government.

In 2015, Philips received new and troubling information from overseas. Another Royal Philips subsidiary received complaints about degrading foam in Japan, where Philips had delivered ventilators for adults and children.

Philips could have alerted customers and federal regulators or moved to repair all of its machines. Instead, the machines were repaired in Japan but Philips kept using the foam everywhere else, government records show.

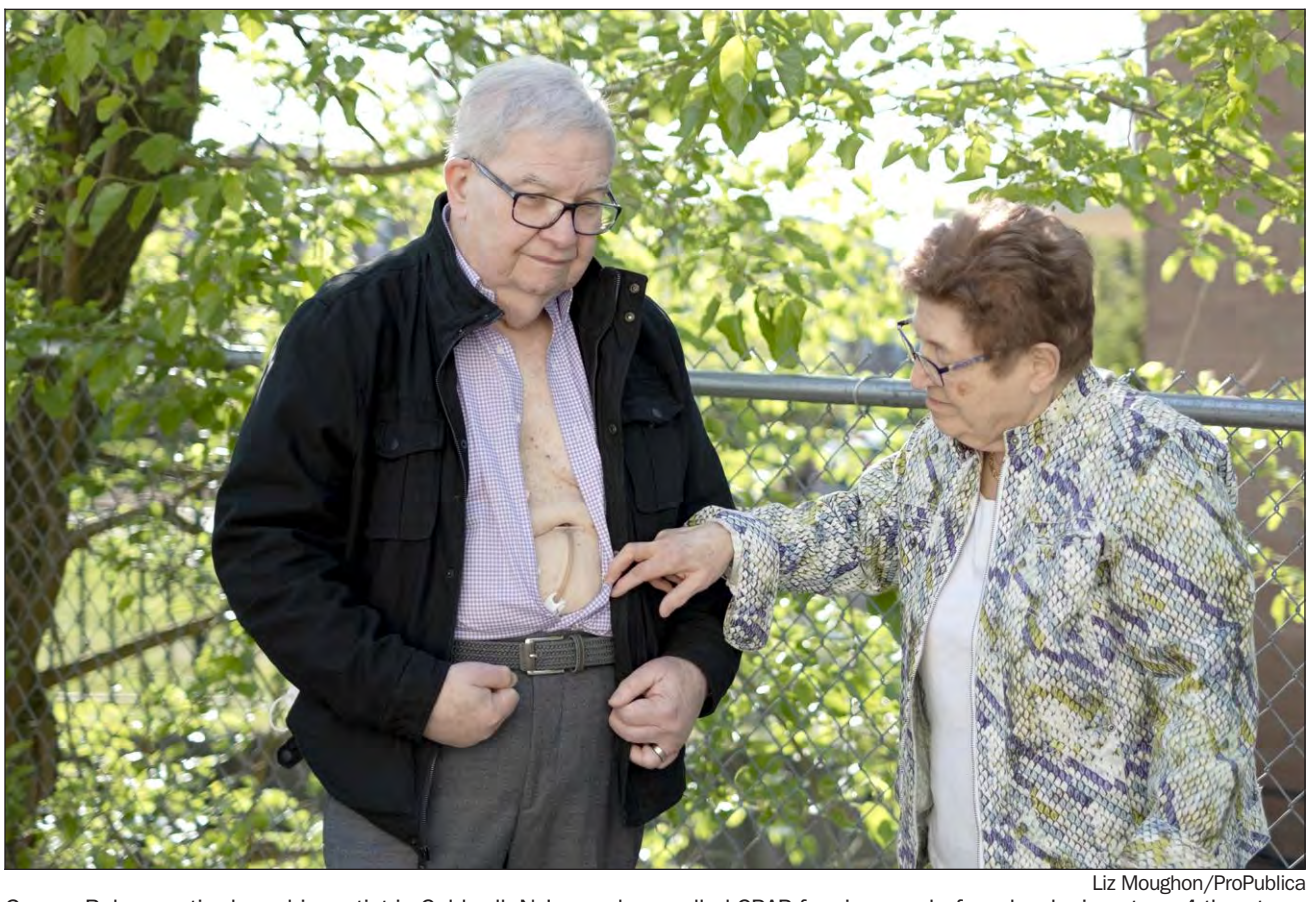
That same year, graphic artist and painter George Bales put a Philips CPAP machine on a nightstand in his New Jersey home, unaware of the foam hidden inside the device. Every night for the next six years, he used the machine as he slept next to his wife of 34 years, a pediatrician who used to nudge him awake to make sure he was breathing.

> **"No one ever informed me that this machine might be killing me."**
>
> **George Bales**

Long retired, Mr. Bales spent hours in the kitchen, perfecting his marinara sauce for dinner parties, until he developed a sore throat and congestion that wouldn't go away in 2021.

Doctors found a malignant tumor near one of his vocal cords. Mr. Bales, who now has trouble swallowing and uses a feeding tube inserted just above his belly button, acknowledges he may never know whether the recalled machine caused his cancer. But he said the company should have warned customers years earlier.

"No one ever informed me that this machine might be killing me," said Mr. Bales, 78, who is suing Philips. "I'm now suspicious of everything I take into my body."



Liz Moughon/ProPublica

George Bales a retired graphics artist in Caldwell, N.J., used a recalled CPAP for six years before developing stage 4 throat cancer. He now eats with a feeding tube. He says his wife, Dr. Susan Bales, a pediatrician, has remained a constant source of support throughout his ordeal.

ELVIS AND AIR FRYERS

As complaints inundated the company, Philips launched marketing campaigns to sell its devices around the world, from Toronto to Sydney. In Brazil, one doctor prescribed the machines to 1,200 patients — the youngest just 6 months old.

The company showed up at international health conferences in Berlin and Dubai to promote the devices, in one case with the help of an Elvis impersonator.

In advertisements Philips declared that its CPAP machines were far quieter than those put out by its top competitor. "Rediscover dreams," the company said. In 2017, Philips offered free air fryers to anyone who bought an $800 DreamStation.

"From the very beginning, they wanted to put CPAPs in the supermarket as a long-term project," said Laura Adorni, a former sales director at Philips in Italy. "They already had razors, toothbrushes, aerosol devices in pharmacies and shops, so why not also have a CPAP?"

As the company promoted its machines, Philips cut deals, beginning in 2012, with local medical equipment suppliers that sell the devices directly to patients — drawing the attention of federal investigators.

In one case, the government accused Philips of giving suppliers in 2014 a coveted database about the prescribing practices of doctors.

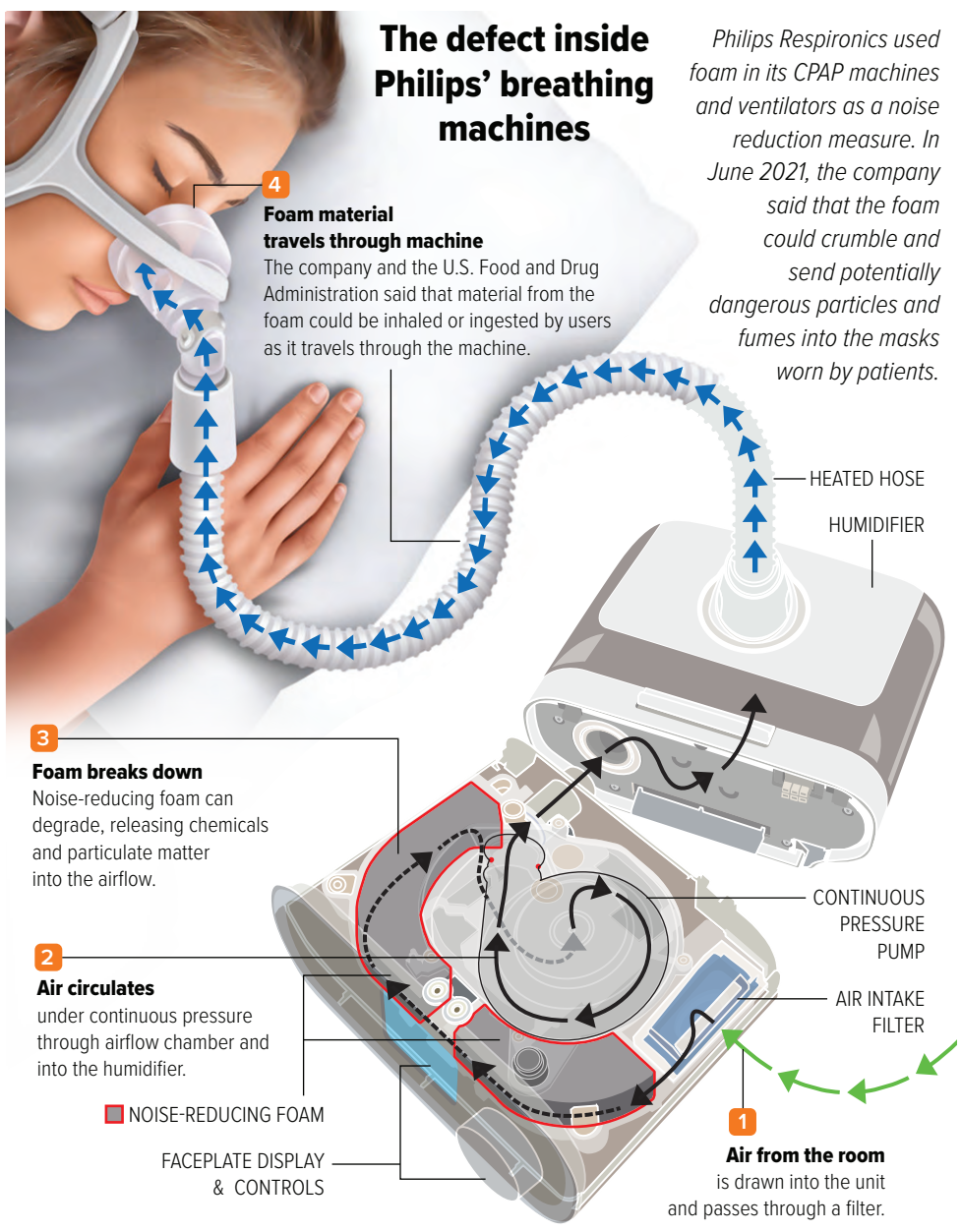
In exchange, prosecutors said, Philips expected the suppliers to recommend the company's breathing machines, which are often paid for through Medicare and other public programs.

"Move … share in our direction," a sales director at Philips wrote in an email to his team about the arrangement.

SEE **CPAP**, PAGE A-14

The defect inside Philips' breathing machines

Philips Respironics used foam in its CPAP machines and ventilators as a noise reduction measure. In June 2021, the company said that the foam could crumble and send potentially dangerous particles and fumes into the masks worn by patients.



Source: Royal Philips

James Hilston, Ed Yozwick/Post-Gazette

U.S. District Court of W. Pa. exhibit

Philips promoted its popular DreamStation with the slogan "Rediscover dreams" in this advertisement in 2016, even after complaints poured into the company about foam degrading inside the machines, which are used by fragile patients in homes and hospitals.

Inside Philips, an unfolding crisis

As one of the world's leading manufacturers of CPAPs and ventilators, Philips Respironics made a fateful decision more than a decade ago: Fitting polyester-based polyurethane (PE-PUR) foam inside the chambers of its breathing devices to reduce noise. What followed would throw the company into turmoil, draw international criticism and threaten the health of millions of vulnerable people.

Scan this code for an interactive timeline of the breathing machine crisis.

1980

Respironics founder Gerald McGinnis opened the company's first manufacturing facility for anesthesia masks in Murrysville and designed his own version of a CPAP.

1985

Respironics commercializes the technology and sells the first publicly available CPAP device.

March 2008

Amsterdam-based Royal Philips, widely known as a maker of televisions and other electronics, takes control of Respironics after threatening a hostile takeover.

PHILIPS RESPIRONICS

2009

The new subsidiary, Philips Respironics, which produces its breathing machines in two suburban Pittsburgh plants, inserts a polyester-based polyurethane foam into its ventilators and CPAPs to reduce noise.

May 2010

Philips receives one of the earliest reports of problems related to the foam. Over the next 11 years, more than 3,700 complaints would bombard the company. Most were not passed on to the Food and Drug Administration, despite a federal law that requires medical device makers to report defects that can injure or kill patients.

June 2010

Philips receives a complaint that describes "contamination of white foam particles" in a ventilator.

Oct. 2015

Philips receives information from Japan about foam breaking down in the company's ventilators. Subsequent tests show the material can degrade in heat and humidity. The company moves to replace the foam in Japan, but does not repair millions of other machines with the same problem foam.

1980 '81 '82 '83 '84 1985 2008 2009 2010 '11 '12 '13 '14 2015 2016

Sources: Royal Philips internal emails, Post-Gazette archive, court filings

Research: Mike Sallah, graphic: Ed Yozwick/Post-Gazette

CPAP, FROM A-13

Prosecutors later alleged that the exchange of the database — which can cost more than $100,000 — amounted to an illegal kickback scheme and reached a settlement with Philips, which eventually paid $24 million without admitting wrongdoing. In its statement to the news organizations, the company said it agreed to settle to avoid the expense of further litigation.

In 2015, Philips was moving to dominate the market, but its emerging foam problem threatened the momentum. That year, a company engineer emailed the foam supplier, saying: "I have never seen this happen to foam we have here," company records show.

Two and a half years later, as new complaints came in from Australia, Philips scientists were summoned to a series of emergency meetings outside Pittsburgh to come up with a plan. The day after one of the sessions, another engineer detailed the safety risk in an email to the foam supplier.

"The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users," engineer Vincent Testa wrote that April, sharing photos of the foam breaking apart. "I flagged this message with high importance since we are addressing a potential safety concern."

Without alerting the FDA or the public, the company started replacing the foam in some ventilators but once again left the vast majority of machines untouched, including the widely used DreamStation, FDA records show. Mr. Testa did not respond to interview requests.

Customers weren't told even as debris turned up on their bedsheets, pillows and faces.

Outside Indianapolis, Connie Thompson slept every night with a DreamStation by her side, next to a blanket with a picture of the Disney character Elsa.

She got the machine to treat sleep apnea while she was still in high school and used soap and water to clean out the black particles that started showing up in the tube connected to her mask, she said. Ms. Thompson, a community activist who fought for safe drinking water in her hometown, said she had no idea about the menace in her own bedroom.

"It's almost like a betrayal," said Ms. Thompson, now a 24-year-old college student studying public safety.

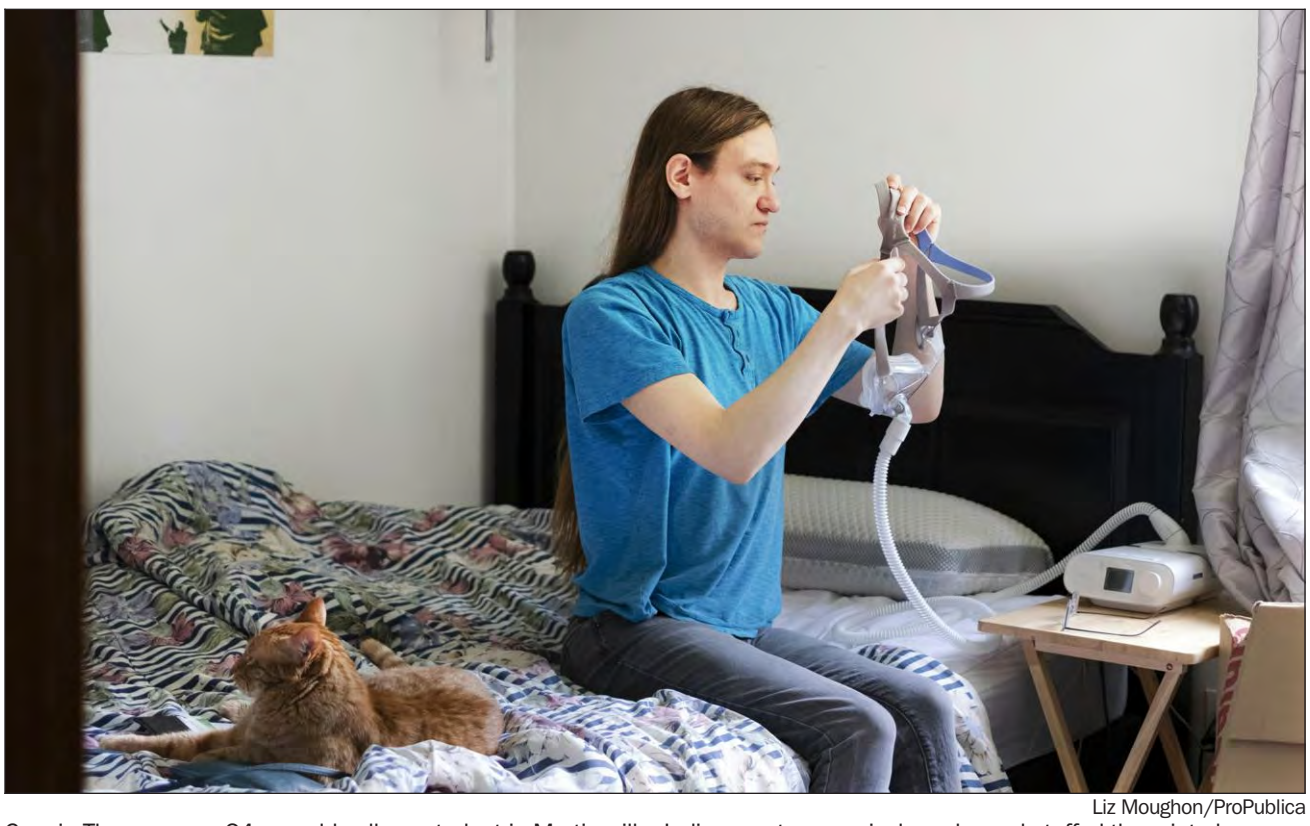
South of Baton Rouge in the Iberville Parish of Louisiana, 62-year-old Sheriff Brett Stassi said he regularly found black particles on his pillow.

He spent four years using a DreamStation before he was diagnosed with kidney cancer, rushed into surgery and put on a rigorous course of treatment. After the recall, Sheriff Stassi said he learned from the FDA and others that some of the particles released by the foam could harm the kidneys and liver.

He is hoping to complete his fourth term as sheriff before he retires to spend more time with his grandchildren, whose pictures fill his wood-paneled office, and to cheer on his beloved Louisiana State University football team.

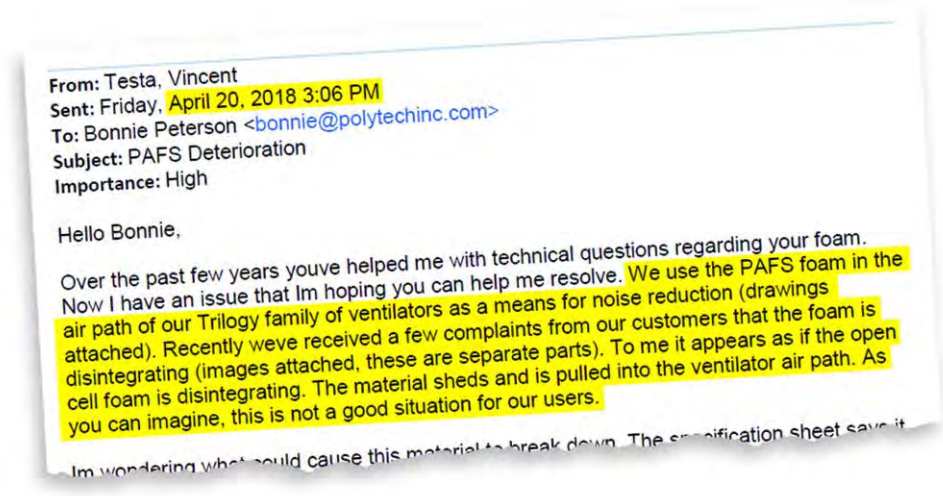
As a longtime investigator, Sheriff Stassi said he's baffled by the company's decisions.

"They knew about it, did nothing about it and then started working on a fix," said Sheriff Stassi, who is suing Philips. "People matter. You only get one chance to do it right."



Liz Moughon/ProPublica

Connie Thompson, a 24-year-old college student in Martinsville, Indiana, cut up surgical masks and stuffed them into her CPAP to try to trap the black debris that she saw in the breathing tube.



From: Testa, Vincent
Sent: Friday, April 20, 2018 3:06 PM
To: Bonnie Peterson <bonnie@polytechinc.com>
Subject: PAFS Deterioration
Importance: High

Hello Bonnie,

Over the past few years youve helped me with technical questions regarding your foam. Now I have an issue that Im hoping you can help me resolve. We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction (drawings attached). Recently weve received a few complaints from our customers that the foam is disintegrating (images attached, these are separate parts). To me it appears as if the open cell foam is disintegrating. The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users.

Im wondering what could cause this material to break down. The specification sheet says it

U.S. District Court of Western Pa. exhibit; photo illustration: James Hilston/Post-Gazette

A mechanical engineer at Philips raised an alarm (highlighting added) in an email message about the foam disintegrating.

THE COVID-19 SURGE

As the pandemic erupted and countries raced to gather ventilators to fight a virus that attacked the lungs, Philips was well positioned to meet the demand.

In March 2020, the company reached out to the U.S. government.

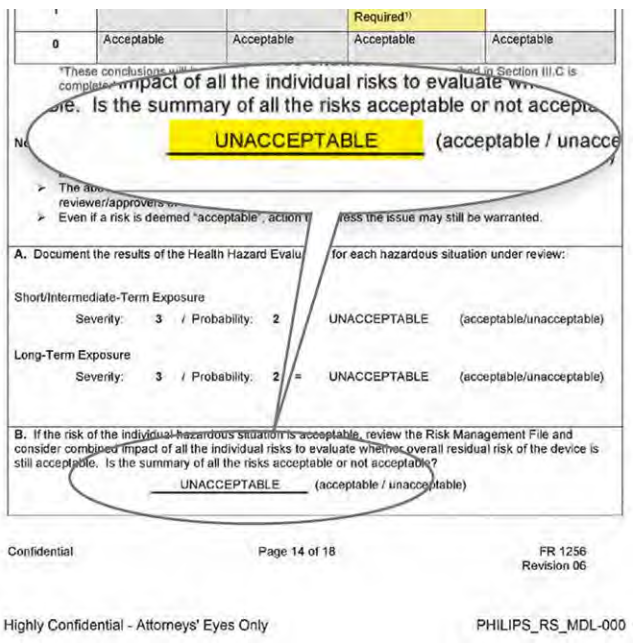
Nathan Naylor, a Philips vice president, emailed the Department of Veterans Affairs describing the company's extensive catalog of ventilators, including the V30, which featured alarms and nine settings for sick patients.

"Good for America," Pamela Powers, the agency's then chief of staff, wrote two weeks later. "We appreciate your company's partnership for sure."

That ventilator, however, was built with the problem foam and was among the 20 models of Philips breathing machines that were later recalled. In an email, the VA said it did not know about the foam until the recall and could not comment on the email exchange.

The agency said it distributed several hundred thousand of the now-recalled machines over the years but did not say whether any were the V30s.

Mr. Naylor is no longer with the company and did not respond to interview requests.



			Required[1]	
0	Acceptable	Acceptable	Acceptable	Acceptable

[1]These conclusions will impact all of the individual risks to evaluate
re. Is the summary of all the risks acceptable or not accepta

UNACCEPTABLE (acceptable / unacce

- The above reviewer/approvers
- Even if a risk is deemed "acceptable", action to address the issue may still be warranted.

A. Document the results of the Health Hazard Evalu for each hazardous situation under review:

Short/Intermediate-Term Exposure
Severity: 3 / Probability: 2 UNACCEPTABLE (acceptable/unacceptable)

Long-Term Exposure
Severity: 3 / Probability: 2 = UNACCEPTABLE (acceptable/unacceptable)

B. If the risk of the individual hazardous situation is acceptable, review the Risk Management File and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?

UNACCEPTABLE (acceptable / unacceptable)

Confidential Page 14 of 18 FR 1256 Revision 06

Highly Confidential - Attorneys' Eyes Only PHILIPS_RS_MDL-000

U.S. District Court of Western Pa. exhibit; Photo illustration: James Hilston/Post-Gazette

A confidential internal Philips Respironics study between November 2020 and April 2021 assessed the health risks of degraded PE-PUR foam as "unacceptable" (highlight added)

As the COVID-19 virus raged and thousands died in the spring of 2020, Philips boosted production of another ventilator to help ease the burden on overwhelmed intensive care units.

These, too, were built with the same foam.

Over the course of the year, operating profits from ventilators, CPAP machines and other devices soared to about $775 million, more than double what they were the year before, according to reports by Philips' parent company.

Response from customers "remains very positive, resulting in market share gains," Royal Philips' then-CEO Frans van Houten said during a fourth-quarter earnings call.

During the call, Mr. van Houten made no mention of the turmoil inside the company, including internal studies that showed the DreamStation had failed emissions testing for volatile organic compounds.

The chemicals can be found in everyday products, such as gasoline, paints and pesticides, but in breathing machines, the fumes can be inhaled for hours at a stretch.

"You just flooded the market with a product that had a problem," said the former Philips compliance supervisor. "I knew it was bad. They should have fixed the problem early, a decade ago, when they had the chance."

When contacted, Mr. van Houten said he was preparing a response but later declined to comment.

As the pandemic wore on, Philips carried out a series of new studies on the foam — all with bleak results.

About a dozen company officials in 2020 took part in two "health hazard" evaluations, including Gary Lotz, the head of global clinical and scientific affairs, Andy Zeltwanger, director of regulatory affairs, Erin Levering, medical safety manager, Neal Pry, manager of quality engineering, and Doug Roberts, design quality engineer in safety risk management, company records show.

The evaluations were approved by top officials, including Rodney Mell, head of quality for sleep and respiratory care, and Dr. John Cronin, the unit's medical leader.

None responded to requests for comment.

The evaluations showed that the deteriorating foam and the chemicals released by the material could cause "serious injury, life-threatening or permanent impairment."

Both summed up the risk with a single word in capital letters: "UNACCEPTABLE."

MOUNTING INJURIES

Inside Philips, engineers were working on another new device that would ultimately replace the company's signature DreamStation.

In April 2021, Philips unveiled the DreamStation 2, a sleeker and more advanced model with a color touch screen and more personalized settings. Another change separated the new model from the old one: Philips chose different foam, one that would hold up in heat and humidity.

With the launch of the new device, the company's stock price reached a high of $61 a share — more than double what it was five years earlier.

It was only then, during a late-April earnings call with investors, that Philips for the first time revealed that the foam it had used for years in millions of machines was at risk of breaking down.

"Regretfully, we have identified possible risks," said then-CEO Mr. van Houten, adding that the company had set aside 250 million euros to deal with the problem. "We are taking proactive action here."

Mr. Van Houten went on to reassure investors: "The device is safe to be continued to use to the best of our knowledge at this time."

The company alerted the FDA but said nothing to its customers — news reports at the time were largely limited to the company's positive earnings. Over the next six weeks, more complaints came in, one after another:

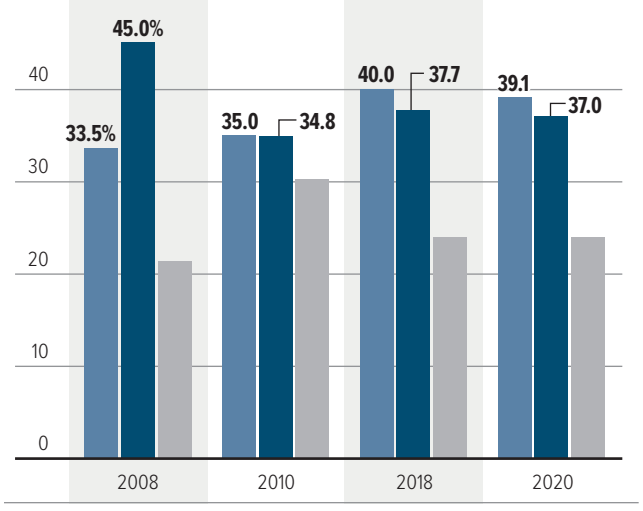
"Black particles are found

SEE **CPAP**, PAGE A-15

Battle for breathing machine supremacy

Philips, ResMed compete for sleep apnea device market share in U.S.

With several companies competing in the sleep apnea industry, Philips continued to sell its devices with the defective foam, even after the company was alerted to the health hazards of its popular CPAPs.



Source: iData Research Inc James Hilston/Post-Gazette

2016

- Philips touts the DreamStation: "Quiet Comfort." "We all want a little peace and quiet at bedtime."
- The company has the most prescribed CPAP systems by U.S. sleep physicians, according to a company survey.

Aug. 2016

- In an email exchange, the foam manufacturer tells the company that supplied the foam to Philips that the material could degrade in heat and humidity. The foam supplier promises to alert Philips to the problem.
- Philips conducts tests that find the foam "shows bad resistance against high humidity in combination with high temperature."

Jan. 2017

Philips promotes its premiere product, the DreamStation, at a conference in Las Vegas.

Oct. 2017

Royal Philips stock hits $42.10 per share – the highest total in almost a decade.

April 20, 2018

In an email, a mechanical engineer at Philips acknowledges a safety concern about the foam. *"It appears as if the open cell foam is disintegrating,"* Vincent Testa wrote to the foam's distributor. *"... This is not a good situation for our users. ... I flagged this message with high importance since we are addressing a potential safety concern."*

May 2018

Testa at Philips sends an email to the foam supplier, saying the company is *"evaluating our options regarding the foam."*

March 2020

In a series of emails at the outset of the COVID pandemic, Nathan Naylor, a Philips vice president, reaches out to the Department of Veterans Affairs and describes a new ventilator that features hospital-grade alarms and nine different settings for sick patients – and filled with the dangerous foam.

April 2020

Royal Philips has 37% of the market share in the U.S. for sleep apnea devices. The company is the leader that year in ventilator sales, controlling 25% of the U.S. market.

2016 2017 2018 2019 2020

CPAP, FROM A-14

in the filter. She had been spitting green phlegm," noted one report in May.

Another report in June: "Caused the patient to develop lung nodules."

Not until the middle of that month did the company announce a voluntary recall, acknowledging that the foam could release chemicals or break into particles capable of causing life-threatening injuries.

Philips said potential health problems included asthma, dizziness, vomiting, respiratory-tract irritation and "adverse effects" to organs including the kidneys and liver. The company also said the material could present a cancer risk.

"It's one of the two or three worst things I have ever seen," said Dr. Sidney Wolfe, a longtime medical researcher and founder of Public Citizen's Health Research Group in Washington, D.C. "It was unacceptable to sell these machines."

The true extent of the crisis may not be known for years.

As news of the problem spread, customers and others stepped forward by the thousands, describing emergency room visits and sudden illnesses in reports submitted to Philips and the government. The reports detailed nearly 2,000 cases of cancer, 600 liver and kidney illnesses and 17,000 respiratory ailments.

"Recurring sinus infections, inflammation, chest pain," one CPAP user wrote in July 2021.

"I have constant headaches," another said in December. "Now I am living with my own hell on earth."

In several cases, the reports described patients who inhaled pieces of foam.

"Caused a patient to vomit," one report said that month. "The patient was unable to remove the mask and expired."

In a Philadelphia apartment he shares with two cats, lawyer Roger Traversa broke several ribs while coughing two years ago. In the hospital, doctors drained 2½ liters of fluid from the wall of his lungs.

After his CPAP machine was recalled, he went to a local flea market and spent $60 on another device made by a Philips competitor.

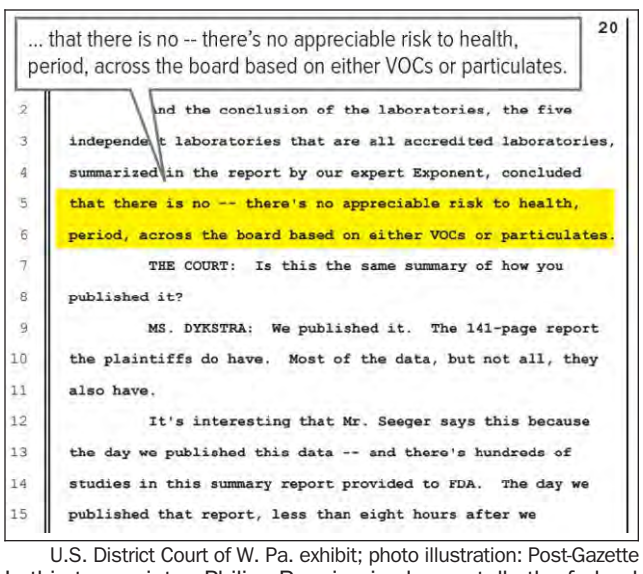
"I feel much better," said Mr. Traversa, who is also a plaintiff in the ongoing lawsuits. "Now I can go … most of the day without having a coughing fit that drives people nuts. It was a great relief."

Philips said the reports of illnesses and injuries are not evidence that its devices caused harm. Six medical experts who spoke to the Post-Gazette and ProPublica said the complaints are an indisputable indicator of a sprawling public health crisis. They said more harm is likely to emerge in coming years, much as the full effects of tobacco or asbestos only became clear decades later.

"If you shoot tiny ping pongs down airways to obstruct the lungs, you can imagine the potential consequences," said Dr. Robert Lowe, a retired emergency room physician and public health researcher in Oregon who used a DreamStation before it was recalled.

Liz Moughon/ProPublica

Army veteran Jules Lee, 56, said he stopped using his Philips CPAP machine six months before the recall, but he has sleep apnea and worries about dying in his sleep.



... that there is no -- there's no appreciable risk to health, period, across the board based on either VOCs or particulates.

20

and the conclusion of the laboratories, the five independent laboratories that are all accredited laboratories, summarized in the report by our expert Exponent, concluded that there is no -- there's no appreciable risk to health, period, across the board based on either VOCs or particulates.

THE COURT: Is this the same summary of how you published it?

MS. DYKSTRA: We published it. The 141-page report the plaintiffs do have. Most of the data, but not all, they also have.

It's interesting that Mr. Seeger says this because the day we published this data -- and there's hundreds of studies in this summary report provided to FDA. The day we published that report, less than eight hours after we

U.S. District Court of W. Pa. exhibit; photo illustration: Post-Gazette

In this transcript, a Philips Respironics lawyer tells the federal court in Pittsburgh in June that tests ordered by the company found "no appreciable risk to health" from its CPAP machines. (highlight added)

Courtesy of Roger Traversa

Doctors drained 2½ liters of fluid from Roger Traversa's lungs after he coughed so hard he broke ribs from what he believes was severe irritation caused by the degraded foam in his DreamStation CPAP machine.

Philips has pointed to studies from France and Canada that found Philips CPAP users were not at higher risk of cancer. But those studies described limitations: The analysis in Canada lacked information about whether patients used their machines regularly and the researchers in France acknowledged that more time and a larger sample size would be needed to produce definitive results.

John James, former chief toxicologist for NASA, said it's far too early to assess how much damage has been done.

"You can't trivialize the problem," said Mr. James, who was responsible for ensuring that astronauts had clean air. "You're basically putting this in the air stream of a human being breathing straight through that material."

Other claims by Philips have also been met with skepticism.

The company has frequently pointed to an ozone cleaner used by some customers to disinfect their devices, saying the product accelerated the breakdown of the foam. But the FDA has said that the machines themselves, not the cleaners, presented "unreasonable risk to patients."

Philips has also said that only a small number of recalled machines showed evidence of disintegrating foam after a visual inspection. But a 2021 report by experts in the company, obtained by the Post-Gazette and ProPublica, concluded that there was no way to tell by simply looking how much the foam had broken down.

Since the recall, the company has said that testing on the DreamStation and similar devices shows the chemicals released by the foam — including phenol, which can cause lung damage and dizziness — are not at levels that can cause "appreciable harm" to patients.

The company acknowledges that the foam tested positive for genotoxicity — its own experts described "uncontrolled cellular replication" — but said that a third-party assessment still concluded the machines are unlikely to cause harm.

The three experts consulted by the news organizations said that's not possible. While safety thresholds for chemical emissions vary and findings can be open to interpretation, genotoxicity means that one or more chemicals are changing cells, the building blocks of the human body.

"You can't make the argument that it's safe. That's bad science," said the engineer involved in the Philips testing. "It's a real-life failure that shows you have a problem. There's no ambiguity. There is unacceptable risk. Full stop."

The company's ventilators also tested positive for genotoxicity; Philips said the devices are still being assessed.

These safety claims have raised concerns among employees and others involved in the testing, interviews and text messages show. In August 2021, two months after the recall, one Philips engineer sent a series of texts to a colleague about a lab hired by Philips to test the foam.

"It was obvious that he was trying to pass the device by any method that would work," the engineer wrote.

In its statement, Philips said the tests were conducted "in the most rigorous and objective manner possible."

Documents related to the testing were turned over to the Justice Department earlier this year in what has become a sweeping investigation into the company's testing practices and safety claims, according to sources familiar with the matter. Through a spokesperson, the Justice Department declined to comment.

Philips has acknowledged that it is in discussions with federal prosecutors and that the company received a subpoena last year for information about the events leading up to the recall.

'ALL ABOUT MONEY'

Now, more than two years after the recall announcement, patients say they are desperate for information about what went wrong.

In Louisiana, 56-year-old Army veteran Jules Lee said he still doesn't know whether his nagging headaches and sinus congestion were caused by the Philips CPAP machine that he used for three years. He stopped using it about six months before the recall even though he suffers from sleep apnea and worries about dying in his sleep.

"I'm fearful and untrusting," said Mr. Lee, who struggles with post-traumatic stress disorder after serving in the Gulf War in the early 1990s.

More details about the health risks are expected to emerge through the ongoing federal lawsuits in Pittsburgh. Last month, the company reached a settlement in one case, agreeing to pay at least $479 million to reimburse customers and others for the costs of the defective machines.

Other legal challenges are still ongoing, including a number of personal injury claims and a class-action suit seeking ongoing medical monitoring and research on the dangers posed by the devices. In court documents, the company argued that the lawsuits failed to prove the machines were responsible for injuries and illnesses.

In recent months, parent company Royal Philips has sought to distance itself from the crisis. During a shareholder's meeting in May, new CEO Mr. Jakobs said the U.S. subsidiary had received complaints about the devices beginning in 2015. "They did some action and they closed it and carried on," he said, without elaborating.

Mr. Jakobs himself, however, was in charge of overhauling the division that makes sleep apnea machines and ventilators as the internal crisis unfolded and as Philips was pitching devices that contained the foam during the pandemic. Through the company, Mr. Jakobs did not respond to interview requests.

Two former company managers said it's likely officials in Amsterdam were aware of the crisis, given the scale of the problem and the importance of the devices to the company's bottom line.

"I truly believe those folks knew about it all along," said the former regulatory supervisor at Philips. "They tried to keep it pinned down as much as possible."

Mr. McGinnis, the founder of Respironics, said Philips breached a fundamental tenet in the medical device industry by not acknowledging the problem early on.

"We had a lot of products we had to shut down," he said. "You worry about it, think about it, look into it. You have to take on the responsibility. You can't blame it on somebody else."

In New York, Mr. Edwards, the longtime music teacher, is still recovering from his second throat surgery. He spends most of his time in an apartment he shares with his wife and dogs. Drumsticks from his years as a heavy metal rocker sit untouched in a display case on the wall.

Now using a refurbished CPAP machine, Mr. Edwards said Philips should be held accountable for failing to warn its customers about the dangerous defect long ago.

"It's all about money to them — that's the bottom line," he said. "One day they'll have to answer for what they've done."

Reporting was contributed by Mike Wereschagin of the Pittsburgh Post-Gazette, as well as Molly Burke, Margaret Fleming, Susanti Sarkar, Nicole Tan, Claire Gardner, Bridgette Adu-Wadier, Aidan Johnstone, Kelly Adkins, Haajrah Gilani, Juliann Ventura and Grant Schwab of Northwestern University's Medill Investigative Lab.

Feb. 2021
In the company's 2020 annual report, Royal Philips does not disclose the problem to investors and the public, but instead says its respiratory products division plays a "crucial role in fulfilling customer needs" during the pandemic.

April 13, 2021
Philips announces the launch of its newest sleep apnea machine, the DreamStation 2. Unlike its predecessor, the new machine was not fitted with the degrading foam.

April 23, 2021
Royal Philips stock peaks at $61.10 a share.

April 26, 2021
In an earnings report, the company for the first time discloses problems with the foam, admitting a "quality issue" and that it had set aside $266 million dollars to deal with the problem.

June 14, 2021
- Philips initiates a voluntary recall in the United States and a field safety notice to the rest of the world.
- Philips issues clinical information for physicians detailing the potential for serious health risks.
- More than 15 million devices are recalled.

June 2021
Complaints inundate the FDA, describing deaths, illnesses, hospitalizations among patients.

July 22, 2021
FDA classifies the recall as Class I, the most serious kind.

Sept. 2021
Philips launches a repair and replacement program for the DreamStation.

Nov. 2021
The FDA releases a scathing inspection report, saying Philips failed to report complaints about the problem machines, adequately evaluate or test the foam or launch a formal investigation.

Sept. 1, 2022
After a lengthy investigation, federal prosecutors allege that Philips had engaged in a kickback scheme with suppliers for years in the sale of its breathing machines. The company agreed to pay $24 million to settle the case, without admitting wrongdoing.

Oct. 2022
Stock prices begin to fall. By Nov. 3, 2022, the price plunges to the lowest level in over 25 years: $11.75 a share.

June 2, 2023
The number of reported deaths associated with machine users is 370, according to reports received by the FDA.

Sept. 7, 2023
Philips Respironics agrees to a $479 million partial settlement on claims over flaws in the company's CPAP machines.

2021 2022 2023